UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte HUGH SHARKEY and GARY FANTON

Appeal No. 2006-0184
Application No. 08/714,987

HEARD: FEBRUARY 9, 2006

Before FRANKFORT, McQUADE and CRAWFORD, Administrative Patent Judges.

FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 48, 50, 53 through 55 and 74 through 94, all of the claims remaining in the application. Claims 1 through 47, 49, 51, 52 and 56 through 73 have been canceled.

Appellants' invention relates to a method and apparatus for delivering thermal energy to a selected collagen containing tissue and effecting a contraction of at least a portion of the collagen containing tissue, and more particularly to a method and apparatus

for contracting a collagen containing tissue that is at least partially adjacent a fluid medium. As noted in the paragraph bridging pages 5 and 6 of the specification, it is an objective of the invention to provide

> "a method and apparatus with a feedback control device configured to deliver sufficient energy to a selected site of a collagen containing tissue positioned at least partially adjacent to a fluid medium to contract at least a portion of the selected site and produce a thermal feedback signal representative of a composite of the thermal energy contents of at least a portion of the selected site and at least a portion of the adjacent fluid medium."

The apparatus includes an energy delivery device configured to deliver a desired level of energy to a selected site of the collagen containing tissue. The energy delivery device includes a distal portion where a sensor is positioned. The sensor provides a signal indicative of the thermal energy content of at least the selected site of the collagen containing tissue and the adjacent fluid medium to a feedback control unit. The feedback control system then adjusts the level of energy supplied to the energy delivery device and delivered to the selected site based on the signal received from the sensor. Independent claims 74 and 89 are representative of the subject matter on appeal and a copy of those claims can be found in the "Appendix of Claims" attached to appellants' brief.

The prior art references relied upon by the examiner in rejecting the appealed claims are:

Cosman '597	4,966,597	Oct. 30, 1990
Makower et al. (Makower)	WO 9315664	Aug. 19, 1993

Cosman et al., "Theoretical Aspects of Radiofrequency Lesions in the Dorsal Root Entry Zone", Neurosurgery, vol. 15, no. 6, pgs. 945-950 (1984).

Claims 48, 50, 53, 74, 75, 77 through 83 and 85 through 88 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Cosman article.

Claims 74, 76, 82 and 84 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Cosman article in view of Cosman '597.

Claims 54, 55 and 74 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Cosman article in view of Makower.

Claims 89 through 94 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower in view of the Cosman article.

Rather than attempt to reiterate the examiner's full commentary with regard to the above-noted rejections and the conflicting viewpoints advanced by the examiner and appellants regarding the rejections, we make reference to the examiner's answer (mailed March 10, 2005) for the reasoning in support of the rejections, and to appellants' brief (filed August 13, 2004) and reply brief (filed May 11, 2005) for the arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by appellants and the examiner. As a consequence of our review, we have made the determinations which follow.

With respect to the rejection of apparatus claims 48, 50, 53, 74, 75, 77 through 83 and 85 through 88 under 35 U.S.C. § 102(b), we note that the Cosman article discloses an apparatus for the delivery of radiofrequency (rf) energy to body tissue located in the brain, spinal cord, and peripheral nervous system to control pain and other neurological disorders. The objective to be achieved

is the formation of a small "heat lesion" in tissue adjacent to the probe, wherein the lesion has a smooth and well-circumscribed boundary surface and neural tissue within the boundary surface is killed so that it can no longer transmit pain signals. The type of apparatus and probe used in the formation of such a "heat lesions" is best shown in Figures 1-3, 5 and 6 of the Cosman article. That apparatus includes an energy delivery device or probe/electrode including a proximal portion connected to an RF generator and a distal portion located adjacent the tissue being treated. The distal portion includes a thermally conductive material in the form of a lesion forming tip to be inserted into the tissue to be treated and the energy delivery device is configured to deliver sufficient energy to a selected site to effect lesion formation.

The Cosman article also discusses the importance of monitoring the probe/electrode temperature in rf lesion making so as to obtain consistent lesion size, indicating that "[t]emperature is the fundamental lesioning parameter" (page 947, col. 1), and that by monitoring the electrode temperature and by choosing the proper electrode size, more consistent and safer lesions can be made. To that end, the Radionics NTCD DREZ electrode shown in Figures 5 and

6 is said to include a sharpened tip "with a built-in thermocouple sensor" (page 948, col. 1).

In the examiner's view, the apparatus of the Cosman article is fully responsive to the apparatus set forth in claims 48, 50, 53, 74, 75, 77 through 83 and 85 through 88 on appeal. While it is true that the Cosman article does not describe use of the apparatus therein in the manner envisioned by appellants, we agree with the examiner that the apparatus is structurally identical to that broadly set forth in the above-enumerated claims and is fully capable of being used in the manner set forth in those claims.

In appellants' view, the apparatus of the Cosman article does not describe or suggest a sensor positioned within the thermally conductive material to detect a thermal energy from a selected site and an adjacent fluid medium, as recited in independent claims 74 and 82. More particularly, appellants contend that the Cosman article is silent as to the position of the sensor that is built into the small, sharpened tip of the device, and that in use (e.g., as shown in Fig. 3) the entire tip is located within tissue being treated. Thus, appellants conclude that the sensor of the Cosman

article is positioned to only detect thermal energy from the selected site, not from an adjacent fluid medium.

We note that independent claims 74 and 82 on appeal, and the claims which depend therefrom, are directed to the apparatus *per se* and not to the particular intended use set forth in the claims. Accordingly, while features of an apparatus may be recited either structurally or functionally, claims directed to the apparatus must distinguish from a prior art apparatus in terms of the structure rather than the function. See, e.g., In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In the case of the apparatus shown in the Cosman article, we agree with the examiner that if the rf probe/electrode therein were positioned so that the thermally conductive tip portion and its enclosed sensor were located in the manner seen in Figure 3 of the present application, i.e., with both tissue of a selected site and adjacent fluid medium in contact with the thermally conductive tip, then the sensor contained within the tip would inherently detect thermal energy from both the selected site and the adjacent fluid medium via conduction through the thermally conductive material of the tip and consequently would as a result thereof produce a thermal feedback signal which represents a composite of the thermal energy

detected from the selected site and from the adjacent fluid medium contacting the probe tip. Contrary to appellants' arguments, this is not an issue of possibilities or probabilities, the thermally conductive probe tip of the Cosman article positioned in the manner described above (i.e., as shown in Figure 3 of the present application) will necessarily produce a signal that is a composite of the thermal energy detected from the selected site and from the adjacent fluid medium contacting the tip.

Moreover, we observe that the energy delivery device of the Cosman article is indicated as delivering a level of energy sufficient to achieve a tip temperature above 45 to 50 degrees C and more particularly of about 75 degrees C. Thus, the energy delivered to the tip in the Cosman article would appear to be sufficient to effect a contraction in at least a portion of collagen containing tissue at a selected site as required in the

claims on appeal[1], although the energy delivery device of the Cosman article is not described as being used in that particular manner.

Having found that the apparatus of the Cosman article is structurally the same as that broadly set forth in independent claims 74 and 82 on appeal, we will sustain the examiner's rejection of those claims under 35 U.S.C. § 102(b). Given appellants' indication on page 3 of the brief that dependent claims 48, 50, 53, 75, 78, 79, 83 and 86 are intended to "rise and fall together" with claims 74 and 82, we also sustain the examiner's rejection of claims 48, 50, 53, 75, 78, 79, 83 and 86 under 35 U.S.C. § 102(b).

Regarding the rejection of dependent claims 77, 80, 81, 85, 87 and 88 under 35 U.S.C. § 102(b) based on the Cosman article, appellants contend (brief, page 5) that the applied reference does

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[1] As indicated on page 15 of appellants' specification, the energy delivery device of the invention is intended to deliver a level of energy necessary to produce a temperature at the tip of between 45 and 90 degrees C. However, a preferred range of temperatures is said to be between 45 to 75 degrees C, just as in the case of the apparatus shown in the Cosman article.

not describe the conductive material as being at a position proximal to the sensor. We do not agree. Given that the sensor in the Cosman article is built into the thermally conductive material tip of the probe/electrode therein (note, e.g., Fig. 6), it is clear that the thermally conductive material extends from a distal tip end of the energy delivery device to a position near or "proximal" to the sensor, as broadly set forth in representative claim 77. Thus, we will sustain the rejection of claim 77 under 35 U.S.C. § 102(b) based on the Cosman article. Given appellants' indication on page 3 of the brief that dependent claims 80, 81, 85, 87 and 88 are intended to "rise and fall together" with claim 77, we also sustain the examiner's rejection of claims 80, 81, 85, 87 and 88 under 35 U.S.C. § 102(b).

Concerning the rejection of claims 74, 76, 82 and 84 under 35 U.S.C. § 103(a) based on the Cosman article and Cosman '597, and of claims 54, 55 and 74 under 35 U.S.C. § 103(a) based on the Cosman article and Makower, we note that appellants contend (brief, page 6) that neither Cosman '597 nor Makower overcome the deficiencies of the Cosman article "discussed above," because neither of those references describe or suggest a sensor positioned within thermally conductive material to detect thermal energy from

a selected site and from an adjacent fluid medium. As we made clear in our discussion of the Cosman article in addressing the examiner's rejection under 35 U.S.C. § 102(b), the argued difference is an inherent property of the probe/electrode described and shown in the Cosman article, especially if it were to be used in the specific manner shown in Figure 3 of the present application. Thus, the fact that the secondary references to Cosman '597 and Makower do not describe or suggest such an arrangement or characteristic is of no moment. Accordingly, the rejection of claims 74, 76, 82 and 84 under 35 U.S.C. § 103(a) based on the Cosman article and Cosman '597, and of claims 54, 55 and 74 under 35 U.S.C. § 103(a) based on the Cosman article and Makower are also sustained.

As for the examiner's rejection of method claims 89 through 94 under 35 U.S.C. § 103(a) based on Makower and the Cosman article, appellants again generally contend that these references do not describe or suggest a sensor positioned within thermally conductive material to detect thermal energy from a selected site and from an adjacent fluid medium (brief, page 6). Our response is the same as above, i.e., that the argued difference is an inherent property of the probe/electrode described and shown in the Cosman article if it

were to be used in the manner shown in Figure 3 of the present application. Thus, that line of argument is not persuasive of any error on the examiner's part. However, appellants have also presented separate arguments directed to dependent claims 90 and 93 on appeal. In that regard, we agree with appellants arguments in the brief and reply brief that neither Makower nor the Cosman article teach or suggest the method steps specifically set forth in claims 90 and 93 on appeal. Thus, the examiner's rejection is sustained as to claims 89 and 94, but not with regard to claims 90 and 93, or claims 91 and 92 which depend from claim 90.

To summarize, we have determined that 1) the rejection of claims 48, 50, 53, 74, 75, 77 through 83 and 85 through 88 under 35 U.S.C. § 102(b) as being anticipated by the Cosman article is sustained; 2) the rejection of claims 74, 76, 82 and 84 under 35 U.S.C. § 103(a) as being unpatentable over the Cosman article in view of Cosman '597 is sustained; and 3) the rejection of claims 54, 55 and 74 under 35 U.S.C. § 103(a) as being unpatentable over the Cosman article in view of Makower is sustained. Concerning the rejection of claims 89 through 94 under 35 U.S.C. § 103(a) as being unpatentable over Makower in view of the Cosman article, that rejection is sustained as to claims 89 and 94, but not with regard

to claims 90 through 93. Thus, the decision of the examiner to reject the claims of the present application is affirmed-in-part.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)(1)(iv).

AFFIRMED-IN-PART

CHARLES E. FRANKFORT)
Administrative Patent Judge)
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JOHN P. McQUADE) BOARD OF PATENT
Administrative Patent Judge) APPEALS
) AND
) INTERFERENCES
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)
)
MURRIEL E. CRAWFORD)
Administrative Patent Judge)

Joel R. Petrow
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116